

5      What is claimed is:

- Sub B1
- 10
1.      A urethral suppository for insertion into a female urethra, said suppository comprising:
- a.      a non-meltable base member having a surface and sized to prevent insertion of said base member into said urethra;
  - b.      a non-meltable reinforcement having a length, said length having a first end and a second end, said first end attached to said base member and projecting from said base member, and
  - c.      a meltable portion formed around a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said second end toward said first end, said meltable portion sized for insertion into said urethra.
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2.      The urethral suppository of claim 1 wherein said base member is shaped for handling by a user of said suppository.
3.      The urethral suppository of claim 1 wherein said base member is an ellipsoid having a major axis substantially perpendicular to the longitudinal axis of the reinforcement.
4.      The urethral suppository of claim 3, wherein said ellipsoid is curved to promote maximal penetration of the meltable portion in the urethra.
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5.      The urethral suppository of claim 1 wherein the base member is grooved to facilitate handling by a user.

5/10/1 6. The urethral suppository of claim 1 wherein the surface of said base member is roughened to reduce slippage of suppository during insertion.

7. The urethral suppository of claim 1 wherein said base member is sized to fit within the labia minora of a patient.

10 8. The urethral suppository of claim 1 wherein said base member is formed from one or more materials selected from the group consisting of synthetic polymer, urethane, cellulose, glass, metal, rubber, and cloth.

9. The urethral suppository of claim 1 wherein said reinforcement first end is embedded within said base member.

10. The urethral suppository of claim 1 wherein said reinforcement projects substantially perpendicular from said base member.

11. The urethral suppository of claim 1 wherein said reinforcement comprises a shape selected from the group consisting of rod, ratchet, helix, and cone.

12. The urethral suppository of claim 11 wherein said shape is comprised of a lattice or mesh.

20 13. The urethral suppository of claim 1 wherein said reinforcement is formed from one or more materials selected from one or more of the groups consisting of urethane, cellulose, glass, metal, rubber, and cloth.

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14. The urethral suppository of claim 1 wherein said reinforcement is sized such that upon insertion of the suppository into the urethra, the second end of said reinforcement is contained entirely within the meltable portion.

15. The urethral suppository of claim 1 wherein the second end of said reinforcement extends outside the meltable portion.

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16. The urethral suppository of claim 1 wherein the length of said reinforcement is greater than the length of the urethra.

17. The urethral suppository of claim 16 wherein said reinforcement is sized for minimal or no contact with the neck of the bladder.

18. The urethral suppository of claim 1 wherein said reinforcement comprises one or more restraints formed along the portion of the length of the reinforcement on which the meltable portion is formed.

19. The urethral suppository of claim 18 wherein said one or more restraints are selected from one or more of the group consisting of protrusions, intrusions, and combinations thereof.

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20. The urethral suppository of claim 19 wherein said protrusions have shapes selected from the group of shapes consisting of spheres, hemispheres, triangles, rectangles, plates, rods, and combinations thereof.

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21. The urethral suppository of claim 19 wherein said intrusions have shapes selected from the group of shapes consisting of spheres, triangles, rectangles, plates, rods, and combinations thereof.

- 5 22. The urethral suppository of claim 1 wherein said meltable portion comprises one or more materials selected from the group consisting of theobroma oil and modified theobroma oil products, glycerinated gelatin, hydrogenated vegetable oils, cellulose, poly (vinyl alcohol), poly (vinylpyrrolidone), polyacrylamide, poly (ethylene glycol), poly (phospho urethanes), polyoxyl stearate and ethylenoxide polymers.
- 10 23. The urethral suppository of claim 1 wherein said meltable portion comprises one or more therapeutic agents selected from one or more of the group of agents consisting of antibiotics, antimicrobials, antifungals, analgesics, anaesthetics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, mucous production inhibitors, hormones, and antispasmodics.
- 15 24. The urethral suppository of claim 1 wherein the diameter of the meltable portion formed around the second end is in the range of about 5 to about 12 millimeters.
- 20 25. The urethral suppository of claim 1 wherein the diameter of the meltable portion formed around the first end is in the range of about 4 to about 10 millimeters.
26. The urethral suppository of claim 1 wherein grooves are formed in said meltable portion.
27. The urethral suppository of claim 26 wherein said grooves are parallel to a longitudinal axis of the meltable portion.
28. The urethral suppository of claim 26 wherein said grooves are helical.
29. The urethral suppository of claim 26 wherein said grooves form a passage for liquid melted from said meltable portion.

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- 5 36. The urethral suppository of claim 35, wherein said ellipsoid is curved to promote maximal penetration of the meltable portion in the urethra.
37. The urethral suppository of claim 33 wherein the surface of said base member is grooved to facilitate handling by a user.
- 10 38. The urethral suppository of claim 33 wherein the surface of said base member is roughened to reduce slippage of suppository during insertion.
39. The urethral suppository of claim 33 wherein said base member is sized to fit within the labia minora of a patient.
40. The urethral suppository of claim 33 wherein said base member is formed from one or more materials selected from the group consisting of synthetic polymer, urethane, cellulose, glass, metal, rubber, and cloth.
41. The urethral suppository of claim 33 wherein said reinforcement projects substantially perpendicular from said base member.
42. The urethral suppository of claim 33 wherein said reinforcement comprises a shape selected from the group consisting of rod, ratchet, helix, and cone.
- 20 43. The urethral suppository of claim 42 wherein said shape is comprised of a lattice or mesh
44. The urethral suppository of claim 33 wherein said reinforcement is formed from one or more materials selected from one or more of the groups consisting of urethane, cellulose, glass, metal, rubber, and cloth.

- 5      45.    The urethral suppository of claim 33 wherein said reinforcement comprises one or more restraints formed along said portion of said length of said reinforcement.
46.    The urethral suppository of claim 45 wherein said restraints are selected from one or more of the group consisting of protrusions and intrusions.
- 10      47.    The urethral suppository of claim 46 wherein said protrusions are selected from one or more of the group of shapes consisting of spheres, hemispheres, triangles, rectangles, plates, and rods.
48.    The urethral suppository of claim 46 wherein said intrusions are selected from one or more of the group of shapes consisting of spheres, hemispheres, triangles, rectangles, plates, and rods.
49.    The urethral suppository of claim 33 wherein said meltable portion comprises one or more materials selected from the group consisting of theobroma oil and modified theobroma oil products, glycerinated gelatin, hydrogenated vegetable oils, cellulose, poly (vinyl alcohol), poly (vinylpyrrolidone), polyacrylamide, poly (ethylene glycol), poly (phospho urethanes), polyoxyl stearate and ethylenoxide polymers.
- 20      50.    The urethral suppository of claim 33 wherein said meltable portion comprises one or more therapeutic agents selected from one or more of the group of agents consisting of antibiotics, antimicrobials, antifungals, analgesics, anaesthetics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, mucous production inhibitors, hormones, and antispasmodics.



5 51. The urethral suppository of claim 33 wherein the maximum diameter of the meltable portion formed around the urethral region is in the range of about 5 to about 12 millimeters.

52. The urethral suppository of claim 33 wherein the diameter of the meltable portion formed around the first end is in the range of about 4 to about 10 millimeters.

10 53. The urethral suppository of claim 33 wherein grooves are formed in said meltable portion.

*Sub B5* 54. The urethral suppository of claim 52 wherein said grooves are parallel to a longitudinal axis of the meltable portion.

55. The urethral suppository of claim 52 wherein said grooves are helical.

56. The urethral suppository of claim 52 wherein said grooves form a passage for liquid melted from said meltable portion.

57. The urethral suppository of claim 33 wherein the length of said taper region is from about 2.5 cm to about 5.0 centimeters.

20 58. The urethral suppository of claim 33 wherein upon insertion, said meltable portion melts within about 2 minutes to about 60 minutes.

*Sub B6* 59. The urethral suppository of claim 33 wherein the length of said reinforcement is greater than the length of said urethra.

5      60.    The urethral suppository of claim 59 wherein said reinforcement is sized for minimal or no contact with the neck of the bladder.

Sub 17

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61.    A method for delivering one or more therapeutic agents to the female urinary tract, said method comprising the steps of:

- a.      inserting the suppository of claims 1 or 32 into the urethra of a female patient;
- b.      waiting a sufficient period for said suppository to deliver one or more therapeutic agents to said urinary tract; and
- c.      removing the non-meltable reinforcement from the urethra.

62.    The method of claim 61 wherein the period ranges from about 1 minutes to about 10 hours.

63.    The method of claim 61 wherein the period ranges from about 2 minutes to about 2 hours.

64.    The method of claim 61 wherein said insertion step comprises grasping the suppository by the non-meltable base member, and positioning the suppository into the urethra wherein the base member sits completely within the labia minora.

- 5 65. A method for manufacturing a reinforced urethral suppository comprising the steps of:
- a. fabricating a single-unit comprising a non-meltable base member sized to prevent insertion of said base member into a female urethra, and a non-meltable reinforcement having a length, said length having a first end and a second end, said first end attached to and projecting from said base member;
- 10 b. forming a meltable portion having a distal end and a proximal end, said meltable portion having a diameter which tapers from said distal end to said proximal end, and comprising one or more therapeutic agents and a biocompatible material; and
- c. combining said non-meltable unit with said meltable portion whereby said meltable portion surrounds a portion of the length of said non-meltable reinforcement.
66. The method of claim 65 wherein said non-meltable base member and said non-meltable reinforcement are fabricated in a single step.
67. The method of claim 65 wherein said non-meltable base member and said non-meltable reinforcement are fabricated separately, and combined to form said single unit.
68. The method of claim 65 wherein said step of combining involves molding said meltable portion around said non-meltable reinforcement.
69. The method of claim 65 wherein said step of combining involves inserting said reinforcement into said meltable portion.
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- 5 70. The method of claim 65 wherein said base member and said reinforcement are independently formed from one or more materials selected from the group consisting of synthetic polymer, urethane, cellulose, glass, metal, rubber, and cloth.
- 10 71. The method of claim 65 wherein said meltable portion comprises one or more materials selected from the group consisting of theobroma oil and modified theobroma oil products, glycerinated gelatin, hydrogenated vegetable oils, cellulose, poly (vinyl alcohol), poly (vinylpyrrolidone), polyacrylamide, poly (ethylene glycol), poly (phospho urethanes), polyoxyl stearate and ethylenoxide polymers.
72. The method of claim 71 wherein said meltable portion further comprises one or more therapeutic agents selected from one or more of the group of agents consisting of antibiotics, antimicrobials, antifungals, analgesics, anaesthetics, steroidal anti-inflammatories, non-steroidal anti-inflammatories, mucous production inhibitors, hormones, and antispasmodics.

Add B7